

# QUANTITY LIMIT PRIOR AUTHORIZATION CRITERIA

<b>DRUG CLASS</b>	<b>TOPICAL CLINDAMYCIN AND ERYTHROMYCIN</b>
<b>BRAND NAME (generic)</b>	<b>CLINDAGEL (clindamycin gel)</b>
	<b>CLEOCIN-T (clindamycin gel, lotion, solution)</b>
	<b>ERYGEL (erythromycin gel)</b>
	<b>(erythromycin solution)</b>
<b>Status: CVS Caremark® Criteria</b>	
<b>Type: Quantity Limit; Post Limit Prior Authorization</b>	

## POLICY

### FDA-APPROVED INDICATIONS

#### **Clindagel**

Clindagel is indicated for topical application in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea, and pseudomembranous colitis, the physician should consider whether other agents are more appropriate.

#### **Cleocin-T Gel, Lotion, Solution**

Cleocin-T Topical Solution, Cleocin-T Topical Gel and Cleocin-T Topical Lotion are indicated in the treatment of acne vulgaris. In view of the potential for diarrhea, bloody diarrhea and pseudomembranous colitis, the physician should consider whether other agents are more appropriate

#### **Erygel**

Erygel Topical Gel is indicated for the topical treatment of acne vulgaris.

#### **Erythromycin Topical Solution**

Erythromycin Topical Solution USP, 2% is indicated for the topical treatment of acne vulgaris.

### INITIAL QUANTITY LIMIT\*\*

#### INITIAL LIMIT QUANTITY

Limits should accumulate across same chemical entity up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

Clindamycin, Erythromycin Topical Limit, Post PA Policy 3697-HJ UDR 04-2023 v2

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PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug	1 Month Limit*	3 Month Limit*
Clindagel (clindamycin gel)	75 mL / 25 days	225 mL / 75 days
Cleocin-T gel (clindamycin gel)	75 gm / 25 days	225 gm / 75 days
Cleocin-T lotion (clindamycin lotion)	60 mL / 25 days	180 mL / 75 days
Cleocin-T solution (clindamycin topical solution)	60 mL / 25 days	180 mL / 75 days
Erygel (erythromycin gel)	60 gm / 25 days	180 gm / 75 days
erythromycin topical solution	60 mL / 25 days	180 mL / 75 days

\*The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.

\*\*If the patient is requesting more than the initial quantity limit, the claim will reject with a message indicating that a prior authorization is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

#### **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the topical treatment of acne vulgaris

**AND**

- The request is NOT for continuation of therapy

**OR**

- The request is for continuation of therapy

**AND**

- The patient has achieved or maintained a positive clinical response as evidenced by improvement (e.g., reduction in number of lesions, etc.)

**AND**

- The requested drug is not being used in a footbath

Quantity Limits apply.

#### **POST LIMIT QUANTITY**

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Drug	1 Month Limit*	3 Month Limit*
Clindagel (clindamycin gel)	150 mL / 25 days	450 mL / 75 days
Cleocin-T gel (clindamycin gel)	150 gm / 25 days	450 gm / 75 days
Cleocin-T lotion (clindamycin lotion)	120 mL / 25 days	360 mL / 75 days

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Cleocin-T solution (clindamycin topical solution)	120 mL / 25 days	360 mL / 75 days
Erygel (erythromycin gel)	120 gm / 25 days	360 gm / 75 days
erythromycin topical solution	120 mL / 25 days	360 mL / 75 days
* The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.		

Duration of Approval (DOA):

- 3697-HJ: Initial therapy DOA: 4 months; Continuation of therapy DOA: 12 months

## REFERENCES

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3. Erygel [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2018.
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5. Lexicomp Online, Lexi-Drugs Online, Hudson, OH: UpToDate, Inc.; 2023; Accessed March 9, 2023.
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9. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74:945-73.
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